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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,955	02/28/2000	Stephen Paul Bryant	1581.059000/RWE	8701

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/514,955

Applicant(s)

BRYANT ET AL

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,26,28-35 and 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,26,28-35 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION*APPLICANTS' ARGUMENTS*

Applicants' arguments in Paper No. 16, filed 24 March 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 25, 26, 28-35 and 37-39. Claims 1-24, 27, 36, and 40-54 have been cancelled as indicated in Paper No. 16, filed 24 March 2003.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph*LACK OF ENABLEMENT*

The rejection of claims 25, 26, 28-35 and 37-39 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention are maintained for reasons of record.

Applicants' argue that the specification teaches confounding factors and manners in which those factors can be factored into a genetic association analysis (page 3, line 14 to page 4, line 9). Additionally, applicants indicate examples wherein "confounding environmental and age related data can be utilized to eliminate the effects of age and environment on variations and phenotype" and "information pertaining to twins can be utilized to remove the effects of age and environment on variation and phenotype" (page 12, lines 14-15; and page 13, line 19 to page 14,

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line 13). It should be noted the indicated limitation(s)/examples are absent from the instant claim(s) language and the claims are not so limited. The specification merely states the information (i.e. factors) "can be utilized" with no further direction as to the implementation of said factors (i.e. manners in which those factors can be factored). The above argument(s) is found unpersuasive and further clarification of the rejection is provided for below.

Claims 25 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as based on a disclosure which is not enabling. Applicants have set forth in claims 25 step(s) that are not provided for by the disclosure as to the procedures and/or limitations required for performing said step(s). While it is acknowledged that the specification does indicate some confounding factors (page 3, line 28 to page 4, line 7), the specification is deficient in guidance as to how one would perform the step(s) of "taking account of the confounding information" (i.e. manners in which those factors can be featured into a genetic association analysis). No guidance is provided for one of skill in the art to utilize confounding factors/information (i.e. algorithm(s)). By what manner(s) does one of skill in the art eliminate the effects of age and environment on variations and phenotype utilizing either 1) confounding environmental and age related data; or 2) information pertaining to twins? For example, absent from the original disclosure are algorithms/methodologies to "take account of" and eliminate the effects of age and environment. Additionally, "if the selected phenotype characteristic is associated with a genotype characteristic in the genotype information for records in the database, whereby the correlation between a phenotype and a genotype is identified." (claim 25, line 7-10), such language implies a calculation (i.e. statistical) for an association to

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correlate a phenotype and a genotype. It is not known what type of correlation analysis or other analysis is to be performed to result in identifying the desired information.

Absent from the original disclosure are algorithms/methodologies to determine an association, wherein said association provides for a correlative value.

Thus, the disclosure is not enabled and an individual skilled in the art would not understand how to perform any of the above steps unless some type of procedure(s) are set forth to provide guidance for the practice of the claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 37 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as necessitated by amendment.

Claim 37 is vague and indefinite as being dependent from a cancelled claim, wherein claim 36 was cancelled in Paper No. 16, filed 24 March 2003. Clarification is requested, via clearer claim language.

Claims Rejected Under 35 U.S.C. § 102

The rejections of claims 25, 26, 28-31, 33, and 37 under 35 U.S.C. § 102 as being clearly anticipated by Perlin et al. (WO 95/21269) are maintained for reasons of record.

Applicants' argument that Perlin et al. is deficient of a single database having a plurality of records (genotype data, phenotype information, and confounding information) thereby utilized

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to generate associations between a phenotype and a genotype is found unpersuasive.

Clarification of the rejection is provided for below.

Perlin et al. describes a method and apparatus for analyzing genetic material by high-throughput genotyping to assess risk for common multi-factorial diseases; wherein the genetic information obtained allows for the tracing of chromosomal segments within families and populations and phenotypic correlation (Abstract; and page 29, lines 12-28). The descent of chromosomal segments within families and populations can be traced utilizing genotyping data and phenotypic data is gathered on the individuals, animals, or plants which are genotyped (pages 49-50, lines 14-31 and 1-3, respectively). The inventors illustrate the steps of obtaining phenotypic and genotypic information, and the determination of the correlation between the data (page 52, lines 3-26 and Figure 12). However, Figure 12 and specification does not require either a single database or multiple databases to have phenotypic or genotypic information and thus the reference can fairly be considered to encompass both forms of databases. Use of single or multiple databases for extracting information for analysis would have been routine in the art at the time of the invention. Thus, Perlin et al. clearly anticipates the claimed invention.

OBJECTION TO DISCLOSURE

The disclosure remains objected to because of the following informalities:

In the specification fails to provide a Brief Description of the Drawings. A separate brief description of each drawing is required.

In the specification on page 11, line 26; page 12, line 21; and page 13, line 9 requires correction: "comprising:-" should be corrected to "comprising:"

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In the specification on page 13, lines 27-29, requires correction, wherein the sentence structure is confusing.

In the specification on page 15 requires correction: "gene" should be replace with "gene;" (line 12); "Identification" should be replaced with "identification" (line 13); and "positions" should be replaced with "positions." (line 18).

Appropriate Correction Is Requested.

No Claims Are Allowed.

ACTION IS FINAL AS NECESSITATED BY AMENDMENT

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

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in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *June 13, 2003*

Examiner Initials: *CSM*

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
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